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10/593,353

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Lars Dahne

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EXAMINER

YEAGER, RAYMOND PHILIP

ART UNIT

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4121

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/593,353	Applicant(s) DAHNE ET AL.	
	Examiner RAYMOND P. YEAGER	Art Unit 4121	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 January 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23-43 is/are pending in the application.
- 4a) Of the above claim(s) 34-43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 September 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>09/19/2006; 01/25/2007</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 23 to 43 are pending.

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372. This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 23 to 33, drawn to a *process of making a core shell particle*.

Group II, claim(s) 34 to 40, drawn to a *core-shell particle*.

Group III, claim(s) 23 to 33 and 43, drawn to a *process of making a microcapsule*.

Group II, claim(s) 41 to 42, drawn to *microcapsule*.

2. As set forth in Rule 13.1 of the Patent Cooperation Treaty (PCT), “the international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept.” Moreover, as stated in PCT rule 13.2, “Where a group of inventions is claimed in one and the same international application, the requirement of unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features.” Furthermore, Rule 13.2 defines “special technical features” as “those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art”

3. The inventions listed as Groups I-II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons.

The special technical feature of Group I is a *process of making a core-shell particle*. The process of using test of claim I does not present a contribution over the prior art. As disclosed in Decher and Schlenoff, 2002, and in view of US Patent Application 2002/0172716 (Published: 11/21/2002) the *process of making a core-shell particle* of instant claim 23 lacks an inventive step.

“*A method for the production of core-shell (CS) particles, comprising:*” – Decher and Schlenoff, 2002 teach the production of nanoparticles resulting from a nanoparticle and a layer-by-layer assembly by deposition of thin films (i.e. nanoparticles-polyelectrolytes; Chapter 8, page 207, abstract, lines 1-4). While Decher and Schlenoff, 2002 teach the importance of a strong adsorption of the first layer is important to anchor the first polymer (Chapter 3, page 94, paragraph 1, lines 8 to 12), Decher and Schlenoff, 2002 do not explicitly teach applying a primer layer to close the pores. ‘716 teaches a method for preparing a core-shell composition (page 13, claim 40) which discloses below the formation of hollow microspheres formed from a porous silica core and a thin polymeric polyelectrolyte shell which will contain bioactive molecules.

- Decher et al., does not teach
 - “*preparing porous templates, the templates being porous organic and/or inorganic microparticles having a diameter of less than 100 μm ;*” – Per MPEP § 2144.05.I. In the case where the claimed ranges “overlap or lie

- inside ranges disclosed by the prior art” a prima facie case of obviousness exists [In re Wertheim, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); In re Woodruff, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990)]. Decher and Schlenoff, 2002 teach nanoparticles are commonly crystallites of inorganic materials with a diameter from 1 to 100 nm (Chapter 8, page 210, paragraph 3, lines 1-2). Decher and Schlenoff, 2002 also teach the coating (core-shell) of colloids (Chapter 12, page 333, paragraph 2, lines 1-4 and page 334, Figure 12.1). ‘716 discloses the microsphere substrate is porous (page 1, paragraph 7) and the microsphere has a diameter from 1 to 100 μm (page 2, paragraph 16). The instant application discloses using silica as a possible template (page 11, paragraph 3). ‘716 claims a core comprising silica (page 13, claim 53).
- *“adsorbing in the porous templates at least one active compound to be encapsulated;”* – Decher and Schlenoff, 2002 teach reagents for layer-by-layer deposition, one of which is proteins (Chapter 1, page 5, Figure 4) and further teach the ability to incorporate enzyme crystals and low molecular weight dyes (Chapter 12, page 332, paragraph 3, lines 10-12). Decher and Schlenoff, 2002, also teach encapsulation of core-shell (Chapter 12, page 333, paragraph 2, lines 11-13). ‘716 gives an example where the microsphere (i.e. template) contains biotin or avidin (page 2, paragraph 17).

- *“applying at least one primer layer to the porous templates; and”* – While ‘716 does not teach a primer layer explicitly, ‘716 does claim a stabilized polymer layer. The instant application discloses the primer layer may be formed with an extra cross-linking step, (e.g. by the means of glutaraldehyde in the case of amino-functionalized polyelectrolytes) (instant case, page 14, paragraph 3, lines 8-11). ‘716 discloses the method where the core-shell composition comprises nanospheres comprising an amine-modified polystyrene and a microsphere comprising glutaraldehyde-activated silica (page 13, claim 46). Since ‘716 claims the same structure as disclosed in the instant case, the properties are expected to be the same.
- *“forming a capsule shell around the porous templates provided with the primer layer by applying coating materials comprising”* – Encapsulation was discussed *supra* per Decher and Schlenoff, 2002
 - *“at least one of alternately charged poly-electrolyte layers and nanoparticle layers to the porous templates, wherein”* – Decher and Schlenoff, 2002 the layer-by-layer application of alternately charged polyelectrolytes (Chapter 12, page 334, Figure 12.1).
 - *“the primer layer is formed from a material which closes pores of the porous templates and is largely impermeable to the coating materials applied in the formation of the capsule shell.”* – Because ‘716 claims the primer layer structure as

stated in the instant application as discussed *supra*, the structures are considered to provide equivalent the function.

Decher and Schlenoff, 2002 teach the well known layer-by-layer technique for the formation of microspheres from nanoparticles and polyelectrolytes. '716 teaches the making microspheres from a porous core-particle by encapsulating with polyelectrolytes in a manner to distribute the layers uniformly and control shell thickness (page 1, paragraph 4). Thus it would have been prima-facie obvious to one of ordinary skill in the art to be motivated to use the basic layer-by-layer techniques and materials disclosed by Decher and Schlenoff, 2002 and modify said technique with teachings of '716 because the '716 patent would allow the encapsulation to be distributed uniformly and be able to control shell thickness.

As such, Group I does not share a special technical feature with the instant claims of Group II. Therefore, the claims are not so linked with the meaning of PCT Rule 13.2 so as to form a single inventive concept, and unity between Groups I-II is broken.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

5. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are

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subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Group Election

During a telephone conversation with Attorney Keith Tacket on 16 January 2009 a provisional election was made **with** traverse to prosecute the invention of group I, a *process of making a core-shell particle*, claims 23 to 33. Affirmation of this election

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must be made by applicant in replying to this Office action. Claims 34 to 43 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention. Also, microcapsules in claims 23 to 33 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Priority

Application 10/593,353 is a national stage entry of PCTUS05/02810 (filed: 03/16/2005) per 35 USC 371 and claims foreign priority to DE 10 2004 013 637.8 (03/19/2004) per 35 U.S.C. 119.

Information Disclosure Statement

The Information Disclosure Statement has been reviewed. Applicants are reminded of their duty to disclose all information known to them to be material to patentability as defined in 37 CFR 1.56. References in non-English languages were only considered when a machine translation was available and are noted as such on the IDS. Neither German Office action was considered because an English translation was not provided.

Objections

The examiner objects to the use of an acronym in the title, CS. The examiner objects to the acronym CS in the claims. For examination purposes the examiner will assert CS means core-shell.

Claim Rejections – 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 30 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 30 reads: "*The method as claimed in claim 23, wherein poly-electrolytes and/or nanoparticles are used **as the at least one active compound** and wherein a surface of the pores is coated by a number of layers of alternately charged poly-electrolytes and/or nanoparticles.*" The claim is understood up to the word "used" but the next fragment, in bold, is incomplete and therefore indefinite.

Claim Rejections – 35 USC § 103

The following is a quotation of 35 USC § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 23 to 29 and 31 to 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Decher and Schlenoff, 2002, in view of US Patent Application 2002/0172716 (Published: 11/21/2002), hereafter referred to as '716.

Instant claim 23:

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- “A method for the production of core-shell (CS) particles, comprising:” – Decher and Schlenoff, 2002 teach the production of nanoparticles resulting from nanoparticles and a layer-by-layer assembly by deposition of thin films (i.e. nanoparticles-polyelectrolytes; Chapter 8, page 207, abstract, lines 1-4). While Decher and Schlenoff, 2002 teach the importance of a strong adsorption of the first layer is important to anchor the first polymer (Chapter 3, page 94, paragraph 1, lines 8 to 12), Decher and Schlenoff, 2002 do not explicitly teach applying a primer layer to close the pores. ‘716 teaches a method for preparing a core-shell composition (page 13, claim 40) which discloses below the formation of hollow microspheres formed from a porous silica core and a thin polymeric polyelectrolyte shell which will contain bioactive molecules.
- Decher et al., does not teach
 - “preparing porous templates, the templates being porous organic and/or inorganic microparticles having a diameter of less than 100 μm ,” – Per MPEP § 2144.05.I. In the case where the claimed ranges “overlap or lie inside ranges disclosed by the prior art” a prima facie case of obviousness exists [In re Wertheim, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); In re Woodruff, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990)]. Decher and Schlenoff, 2002 teach nanoparticles are commonly crystallites of inorganic materials with a diameter from 1 to 100 nm (Chapter 8, page 210, paragraph 3, lines 1-2). Decher and Schlenoff, 2002 also teach the coating (core-shell) of colloids (Chapter 12, page 333, paragraph 2, lines

- 1-4 and page 334, Figure 12.1). '716 discloses the microsphere substrate is porous (page 1, paragraph 7) and the microsphere has a diameter from 1 to 100 μm (page 2, paragraph 16). The instant application discloses using silica as a possible template (page 11, paragraph 3). '716 claims a core comprising silica (page 13, claim 53).
- *“adsorbing in the porous templates at least one active compound to be encapsulated;”* – Decher and Schlenoff, 2002 teach reagents for layer-by-layer deposition, one of which is proteins (Chapter 1, page 5, Figure 4) and further teach the ability to incorporate enzyme crystals and low molecular weight dyes (Chapter 12, page 332, paragraph 3, lines 10-12). Decher and Schlenoff, 2002, also teach encapsulation of core-shell (Chapter 12, page 333, paragraph 2, lines 11-13). '716 gives an example where the microsphere (i.e. template) contains biotin or avidin (page 2, paragraph 17).
 - *“applying at least one primer layer to the porous templates; and”* – While '716 does not teach a primer layer explicitly, '716 does claim a stabilized polymer layer. The instant application discloses the primer layer may be formed with an extra cross-linking step, (e.g. by the means of glutaraldehyde in the case of amino-functionalized polyelectrolytes) (instant case, page 14, paragraph 3, lines 8-11). '716 discloses the method where the core-shell composition comprises nanospheres comprising an amine-modified polystyrene and a microsphere comprising

glutaraldehyde-activated silica (page 13, claim 46). Since '716 claims the same structure as disclosed in the instant case, the properties are expected to be the same.

- *“forming a capsule shell around the porous templates provided with the primer layer by applying coating materials comprising”* – Encapsulation was discussed *supra* per Decher and Schlenoff, 2002
 - *“at least one of alternately charged poly-electrolyte layers and nanoparticle layers to the porous templates, wherein”* – Decher and Schlenoff, 2002 the layer-by-layer application of alternately charged polyelectrolytes (Chapter 12, page 334, Figure 12.1).
 - *“the primer layer is formed from a material which closes pores of the porous templates and is largely impermeable to the coating materials applied in the formation of the capsule shell.”* – Because '716 claims the primer layer structure as stated in the instant application as discussed *supra*, the structures are considered to provide equivalent the function.

Instant claim 24:

- *“The method as claimed in claim 23, wherein the pores have a pore width of 0.3 nm- 100 nm and preferably of 1 nm- 30 nm.”* – '716 discloses pores with a diameter of 10 to 500 nm (page 1, paragraph 7). Per MPEP § 2144.05.I the overlapping ranges make obvious claim 24.

Instant claim 25:

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- “*The method as claimed in claim 23, wherein the templates comprise at least one of porous silica particles, porous zeolite particles, and porous polystyrene particles.*” – Decher and Schlenoff, 2002 make obvious the use of silica and others (Chapter 8, page 210, paragraph 4, lines 13-21) as well as polystyrene (page 215, paragraph 2, line 6). '716 claims silica as noted *supra*.

Instant claim 26:

- “*The method as claimed in claim 25, wherein the porous silica particles range in size from 100 nm to 100 μ m and preferably from 500 nm to 30 μ m.*” – Per MPEP § 2144.05.I the overlapping ranges make obvious the silica particle ranges as discussed *supra* (1 to 100 nm in Decher and Schlenoff, 2002 and 1 to 100 μ m in '716)

Instant claim 27:

- “*The method as claimed in claim 25, wherein the porous zeolite particles have a pore width of 0.3 nm to 10 nm.*” - '716 discloses pores with a diameter of 10 to 500 nm. Per MPEP § 2144.05.I the overlapping ranges make obvious claim 24.

Instant claim 28:

- “*The method as claimed in claim 23, wherein the at least one active compound to be encapsulated comprises at least one of a polymer, a protein, an organic molecule having a molecular weight of over 100 g/mol, a nanoparticle, an enzyme, a catalyst, a dye, a pharmaceutical or cosmetic active compound, and a plant protection agent.*” – As discussed *supra* Decher and Schlenoff make obvious nanoparticles as the template and '716 makes obvious a protein (biotin).

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Instant claim 29:

- *“The method as claimed in claim 23, wherein at least one auxiliary is used for mediating the adsorption of the at least one active compound.”* –In ‘719 a phosphate buffer was used to apply treat the silica microspheres with avidin (page 9, paragraph 103).

Instant claim 31:

- *“The method as claimed in claim 29, wherein the porous templates are prepared in a solution and, additionally or alternatively to the auxiliary, the adsorption of the at least one active compound is controlled by changing the pH of the solution.”* – ‘716 teaches silica microspheres are washed in phosphate buffer (page 8-9, paragraph 101) and this buffer was used to change the pH for avidin binding discussed *supra*.

Instant claim 32:

- *“The method as claimed in claim 23, further comprising dissolving the porous templates after formation of the capsule shell to form the microcapsules.”* – In ‘716 the silica cores are dissolved leaving a hollow sphere (page 5, paragraph 65)

Instant claim 33:

- *“The method as claimed in claim 25, further comprising dissolving silica and/or zeolite templates by fluoride salts in the presence of a buffer solution having a pH between 3.5 and 6.”* – In ‘716 the silica core is removed by chemical etching with an 8 percent aqueous solution of hydrofluoric acid. The pH range cited in the

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instant case is made obvious by the use of hydrofluoric acid in '716 per MPEP 2144.05.II. - Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." [*In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955)]. Thus one of ordinary skill in the art would be expected to optimize the concentration of hydrofluoric acid appropriate to the given working conditions.

Decher and Schlenoff, 2002 teach the well known layer-by-layer technique for the formation of microspheres from nanoparticles and polyelectrolytes. '716 teaches the making of microspheres from a porous core-particle by encapsulating with polyelectrolytes in a manner to distribute the layers uniformly and control shell thickness (page 1, paragraph 4). Thus it would have been prima-facie obvious to one of ordinary skill in the art to be motivated to use the basic layer-by-layer techniques and materials disclosed by Decher and Schlenoff, 2002 and modify said technique with teachings of '716 because the '716 patent would allow the encapsulation to be distributed uniformly and be able to control shell thickness.

Double Patenting

The examiner is aware of US Patent application 10/522,998 with the inventive entity of Daehne, Lars, Baude, Barbara, and Voigt, Andreas. The instant application is drawn to

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the elected group I, a *process of making a core-shell particle*, and does not currently read on a *capsule* as claimed in 10/522,998. The examiner is aware of US Patent application 10/535,714 with the inventive entity of Voigt, Andreas and Daehne. The instant application is drawn to the elected group I, a *process of making a core-shell particle*, and does not currently read on a *process for modifying microparticles* as claimed in 10/535,714.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RAYMOND P. YEAGER whose telephone number is (571)270-7681. The examiner can normally be reached on Mon - Fri 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patrick Nolan can be reached on (571) 272-0847. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

R.P.Y.

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/Patrick J. Nolan/

Supervisory Patent Examiner, Art Unit 4121